

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/756,185	ZICHE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rita Mitra	1653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 8/27/2004.
2. ☒ The allowed claim(s) is/are 11-16, 19-21 and 23-25.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☒ to Paper No./Mail Date 9/3/2002.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br/>Paper No./Mail Date _____</li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</li> <li>6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date _____</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____</li> </ol> |
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## **DETAILED ACTION**

### ***Status of the Claims***

Applicants' supplemental amendment and response (after final) filed on July 19, 2004 is acknowledged. A declaration from Dr. Marina Ziche attached to the supplemental response is also acknowledged. An Exhibit B containing revised Figures 4A and 4B is acknowledged. A subsequent supplemental amendment and response filed on August 27, 2004 is acknowledged. Claims 3, 11, 20, 24 and 25 have been amended. Claims 1, 2, 4-10, 17, 18 and 22 have been canceled. Therefore, claims 3, 11-16, 19-21 and 23-25 are currently pending and are under examination.

### ***Response to Amendments and Remarks***

Rejection of claims 3, 4, 6 and 10-25 as being unpatentable over Borelli, F., taken with Folkman J. in office action dated December 17, 2003 are withdrawn in view of Applicants amendment to claims 19 and 23 in the after final amendment filed on March 17, 2004, and in view of remarks in supplemental amendment filed on July 19, 2004, and in view of amendment to claims 3, 11, 20, 24 and 25 in supplemental amendment filed on August 27, 2004.

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

### ***Examiner's Amendments to the Claims***

Authorization for this examiner's amendment was given in a telephone interview with Attorney Roger Browdy on August 30, 2004.

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The amended claims read as:

- 1-10. Canceled.
11. (Currently amended): A method for promoting angiogenesis in a patient in need thereof, comprising administering to the patient Component B and a human growth factor selected from the group consisting of bFGF and VEGF, for a time sufficient and in amounts effective for the promotion of angiogenesis in the patient, [whereby] wherein said Component B and said human growth factor are administered such that they will be simultaneously present in the blood of the patient in amounts effective for the synergistic promotion of angiogenesis in the patient.
- 17-18. Canceled.
20. (Currently amended): A method of treating a wound, ulcer, or other traumatic lesion in a patient in need thereof, comprising administering the patient Component B and a human growth factor selected from the group consisting of bFGF and VEGF, for a time sufficient and in an amount effective for the treatment of the wound, ulcer or other traumatic lesion in the patient, [whereby] wherein said Component B and said human growth factor are administered such that they will be simultaneously present in the blood of the patient in amounts effective for the synergistic treatment of the wound, ulcer or other traumatic lesion in the patient.
22. Canceled.
24. (Currently amended): A pharmaceutical composition for promoting angiogenesis, comprising Component B and a human growth factor selected from the group

consisting of bFGF and VEGF, in combination with a pharmaceutically acceptable carrier, wherein the ratio of the amount of said Component B to the amount of said human growth factor is selected to provide synergistic angiogenesis results when administered to a patient in need thereof.

25. (Currently amended): A pharmaceutical composition for treating a wound, ulcer, or other traumatic lesion, comprising Component B and a human growth factor selected from the group consisting of bFGF and VEGF, in combination with a pharmaceutically acceptable carrier, wherein the ratio of the amount of said Component B to the amount of said human growth factor is selected to provide synergistic results when administered to a patient in need thereof.

***Reasons for Allowance***

The following is an examiner's statement of reasons for allowance:

The prior art of record does not teach or suggest a pharmaceutical composition and a method of promoting angiogenesis, comprising Component B and a human growth factor, selected from the group consisting of bFGF and VEGF, wherein the ratio of the amount of Component B to the amount of human growth factor provides synergistic angiogenesis results when administered to a patient in need thereof. Further, the prior art does not suggest a pharmaceutical composition and method for treating a wound, ulcer or other traumatic lesion, comprising Component B and a human growth factor, selected from the group consisting of bFGF and VEGF, wherein the ratio of the amount of Component B to the amount of human growth factor provides synergistic results when administered to a patient in need thereof.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

Claims 11-16, 19-21, 23-25 are allowed.

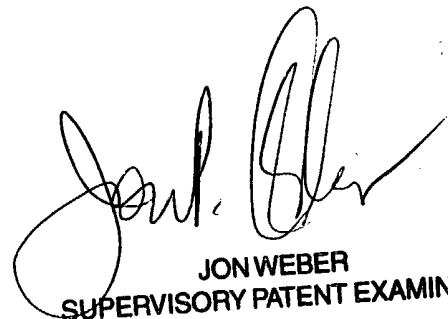
***Inquiries***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (571) 272-0954. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Jon Weber, can be reached at (571) 272-0925. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0547.



Rita Mitra, Ph.D.

August 31, 2004



JON WEBER  
SUPERVISORY PATENT EXAMINER